Competition 2.0: Brands vs. Generics

Innovator and generics companies are colliding as they invade each other's turf to compete more frequently and intensely

Numerous articles have trumpeted the upcoming five-year patent cliff for innovative pharmaceutical companies, during which 18 of the top 20 prescription best sellers—representing over $142 billion in global sales—will face generic competition in the leading developed markets. Unfortunately, these articles fail to tell the more important story: Over the past decade, the frequency and intensity of brand versus generic competition has grown dramatically and will surge globally as the industry continues its transition into the competitive stage of its lifecycle.

There are several reasons for increasing brand versus generic competition. Generics companies have intensified their patent challenges, entered markets earlier, and targeted more off-patent blockbusters, including biosimilars, as well as smaller brands. In addition, generics companies have taken advantage of more supportive laws, regulations, and policies in many markets. At the same time, innovator companies, with weaker pipelines and fewer new products, are trying to extract maximum sales from their existing brands by continuing post-patent promotions. Moreover, innovator companies have focused on emerging markets, where brand versus generic competition is more common.

Increasing generic competition cuts across most products, lifecycle stages, and markets. Generics companies are targeting not only megasellers such as Lipitor and Plavix, but also smaller-selling agents, including some with less than $10 million in sales and 1 percent market share. According to a 2009 Thomson Reuters report, generics companies targeted as many US products with sales less than $50 million dollars as they did blockbuster agents with sales over $1 billion. Over the past five years, generics companies have initiated 65 percent more US patent lawsuits against branded pharmaceuticals and won 70 percent of cases, often resulting in generic copies coming to market years before scheduled patent expirations. In addition, innovator companies are realizing that generic competition in emerging markets can be even more formidable, often with dozens of generic copies for a single brand.

Consequently, most innovator company professionals, who are experienced in brand versus brand competition, need to transfer and enhance their skills to compete against generics companies. It is important for innovator professionals to understand the new dynamics of brand versus generic competition and the potential implications and actions for their companies.

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Braneric Competition

For years, brand and generics companies have competed in virtually distinct worlds, separated by patent protection of branded products, a discrete corporate focus on a single product type, and a wide disparity in prices. However, over the past decade, these two worlds have collided to create a new space, which I term "Braneric Competition." Three competitive factors have catalyzed this fusion.

1) Competitive Duration: Historically, innovators promoted their products against other brands only until the patent expired, at which time multiple generic copies entered the market and often rapidly devoured the brand's market share. Over the past decade, the patent demarcation line has blurred as innovator and generics companies have entered earlier and more aggressively into each other's turf.

Generics companies are no longer waiting for patent expiration to attack originators' products. Teva Pharmaceuticals, the world's largest generics company, has executed over a dozen "at-risk launches" of generic products while patent litigation is pending in the US. In international markets such as Russia, India, and China, some generics companies market brand copies *before* the originator's brand is launched. For example, there were generic versions of the rheumatoid arthritis biologic agent Enbrel in China prior to the launch of the original brand.

For their part, innovator companies are either launching—or authorizing generics partners to launch—generic versions of their brands prior to patent expiry and before competitive generic entry. In addition, originators are now continuing brand promotion long after patent expiration in mature markets or giving them new life by launching into developing markets. Many multinational innovator companies have established mature products divisions specifically de-

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signed to market their off-patent brands. According to IMS, innovators may be able to retain over 50 percent share in some markets and generate over 25 percent of a brand's total value *after* patent expiration. For example, Pfizer, which created an Established Products Division in 2008, has preserved a 60 percent market share in Spain following patent expiration of its cholesterol-lowering agent Lipitor. This combination of earlier generic entry and longer brand promotion has expanded and extended brand versus generic competition.

Corporate Convergence: Previously, most innovator companies focused on commercializing original, branded products while generics companies exclusively sold generic copies. Increasingly, many large branded and generics companies are marketing both types of products. Novartis develops novel agents and sells generic products through its Sandoz division, one of the world's largest generics manufacturers. Sanofi-Aventis, an innovator company, has recently acquired generics manufacturers Zentiva (Czech Republic), Laboratorios Kendrick (Mexico), Medley (Brazil), and Helvepharm (Switzerland). Many other multinational brand companies, including Abbott, Pfizer, and GlaxoSmithKline have partnered with or purchased multiple generics companies. Conversely, generics maker Teva garners over 25 percent of its revenues from novel products, including Copaxone, the world's leading multiple sclerosis brand, and has new products in development for neurology, autoimmune diseases, and oncology.

Commercial Hybridization: As a result of corporate crossbreeding and intensifying competition, branded and generics companies have adopted many of each other's commercial approaches. For example, innovator companies are targeting and offering aggressive commercial terms to distributors and pharmacies, traditionally generic stakeholder strongholds. At the same time, generics companies in some countries are detailing physicians with sales forces that are larger than those of their innovative counterparts.

Perhaps the best example of commercial hybridization is the concept of "branded generics." Prominent innovator and generics companies both promote company-branded products, often stamped with their trusted name on product packages to convey authenticity and quality. For example, GlaxoSmithKline has forged relationships with generics makers in India, South Africa, and other markets to sell branded generics. Similarly, Medley and EMS Sigma Pharma, Brazil's two largest generics makers, have standard corporate brand packaging to appeal to patients. Teva named its first biosimilar agent Tevagrastim, to compete with Amgen's brand drug Neupogen (filgrastim) for severe neutropenia. Some leading generics companies go even further by developing not only "me-too" products but also "me-betters" that are priced and promoted very much like their innovator brand rivals. For example, Sandoz specializes in differentiating complex generic products including injectibles, inhalables, patches, complex oral solids, and biosimilars, for which it has been a global leader.

Winning Innovator Approaches

Braneric competition is changing very quickly and dramatically. Recognizing the need to adapt to this dynamic landscape, successful innovator companies are adopting several approaches to help compete against generic competition:

Planning: The biggest mistake brand professionals make is waiting too long to plan for generic competition. According to a 2009 Thomson Reuters study, nearly half of surveyed pharmaceutical commercial professionals assume that generics companies begin their competitive planning against brands two years prior to patent expiry. In fact, generics companies often initiate competitive planning with targeting brands eight to 10 years earlier, beginning in Phase III or at the launch of an innovative product. The first sign of such competitive activities is a generics company's sourcing of active pharmaceutical ingredients, usually shortly after a brand's launch. Consequently, innovator professionals need to move beyond the relatively limited timeframe of traditional lifecycle management plans, which focus on extending the brand's patent life, and create more comprehensive, longer-term generic competitive plans that extend a *brand's* life. Innovators should develop these plans during a brand's prelaunch phase and update them as part of annual brand planning each year following launch.

Customization: Like their generics competitors who carefully select which brands to target, innovators need to analyze and prioritize potential markets, stakeholders, and competitors. Because every product, market, and competitor set is different, innovators should customize their approach for each situation to determine the appropriate timing, resources, and commitment.

Preparation: Prior to engaging generic competition, some companies utilize competitive simulations, war games, and other types of strategic planning exercises to role play and test strategies and tactics. These simulations can be used during brand versus brand exercises by adding a generics competitor; when competing against a generic copy of a rival brand; or when preparing to compete against the generic version of the company's brand.

Training: Innovator companies need to embed competitive mindsets, expertise, and capabilities throughout their organizations. Progressive brand companies are training not only members of their generic task forces and established brand groups but also a broader set of multidisciplinary professionals to compete with generics companies and products in fair and appropriate ways. These training sessions range from one- to two-day seminars and competition summits to simple lunch-and-learns or expert speaker presentations. PE